

REMARKS

The Office Action mailed April 2, 2008 (hereinafter, "Office Action"), has been reviewed and the Examiner's comments considered. Applicant appreciates the withdrawal of the objections and rejections in view of the Response filed December 28, 2007. Claims 1-32 are pending in this application. No amendments are made herein.

Applicant notes at the outset that the remarks included herein are similar to those found in the Response filed June 25, 2008 in co-pending U.S. Patent Application No. 10/572,191, addressing essentially the same rejection in an office action dated March 25, 2008. The March 25, 2008 office action is submitted herewith in an Information Disclosure Statement.

Claim Rejections – 35 U.S.C. § 103

Claims 1-19 and 21-32 stand rejected under 35 U.S.C. § 103(a) as unpatentable over USPN 6,607,551 to Sullivan et al. (hereinafter, "Sullivan"). Applicant respectfully traverses this rejection.

Each of independent claims 1, 3, 10, 19, and 28 recite a stent including a covering that is deformed by protrusions of a pusher or inner catheter when the covered stent is compressed over the pusher or inner catheter. Each of the independent claims are reproduced in part as follows:

Independent claim 1 is directed to a method of loading a self-expanding stent into a delivery sheath and recites, *inter alia*, "providing said stent as a covered stent. . . a covering material bonded to the matrix lying radially inside the luminal envelope. . . providing a stent pusher in a lumen defined by the stent, the stent pusher having protrusions. . . compressing the stent radially inwardly until the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope" (emphasis added).

Independent claim 3 is directed to a delivery system including a self-expanding stent and recites, *inter alia*, "a pusher within the sheath that extends along the lumen of the stent and has radially outwardly extending protrusions. . . the stent being a covered stent. . . a covering material

bonded to the matrix lying radially inside the luminal envelope. . . the stent being positioned over the protrusions such that the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope” (emphasis added).

Independent claim 10 is directed to a delivery system and recites, *inter alia*, “a self-expanding stent. . . a first covering layer positioned on at least the luminal wall surface. . . an inner catheter. . . including radially outwardly extending protrusions along the distal end that extend into the covering without intersecting a plane along the luminal wall surface” (emphasis added).

Independent claim 19 is directed to a method of loading a self-expanding stent into a delivery sheath and recites, *inter alia*, “the stent including a covering layer on a luminal wall surface. . . providing a stent pusher including protrusions on a distal end thereof; radially compressing the stent over the protrusions such that the protrusions deform the covering layer but do not intersect a plane along the luminal wall surface” (emphasis added).

Independent claim 28 is directed to a method of deploying a stent and recites, *inter alia*, providing a delivery system with the stent loaded in a reduced diameter configuration. . . the stent including a covering positioned on a luminal wall surface thereof, the inner catheter including radially outwardly extending protrusions that extend into the covering” (emphasis added).

The Office Action alleges that Sullivan discloses a stent matrix and graft layers of covering lining the inside and outside of the stent matrix, referring to the passage in the background section of Sullivan that includes the sentence, “[a]s used herein, however, the term “stent” is a shorthand reference referring to a covered or uncovered such stent.” Sullivan, col. 1, ll. 25-27. Presumably from this statement, the Office Action finds disclosure in Sullivan of “protrusions 38 [that] engage the inner surface of the stent graft 34. (Column 3, lines 19-51). . . the protrusions 38 inherently deform the covering material.” Office Action, p. 3. In fact, however, the column 3 passage in Sullivan cited by the Office describes a stabilizer that comprises a plurality of protuberances such that the stabilizer engages peripheral members disposed in succession along the length of the stent through “frictional engagement, or direct mechanical engagement, for example

where the protuberance penetrates an area of open space between peripheral elements of the stent.” Sullivan, col. 3, ll. 29-32.

Thus, contrary to the assertion in the Office Action and despite the general definition in the background section, Sullivan shows and describes a stabilizer with protrusions that contact members of the stent framework, as opposed to deforming a covering material or layer, as claimed.

Support for this fundamental difference between the claimed invention and Sullivan is found throughout the detailed description of Sullivan. For example, the stent 34 is described as comprising “a periphery, such as a wire structure, that defines an interior space therein through which stabilizer 30A or 30B is axially disposed.” Sullivan col. 4, l. 66 to col. 5, l. 1. The stabilizers 30A and 30B are “adapted to engage the inner periphery of stent 34,” the term engaging being defined as “imparting a longitudinal force thereto” to prevent “the accordion-like collapse of the stent, or individual longitudinal sections thereof.” Sullivan, col. 5, ll. 48-55. The stabilizer 30A or 30B (not the stent) comprises a surface element with a high friction surface, such as a covering 138 or a plurality of protuberances 38. *See* Sullivan, col. 5, l. 63 to col. 6, l. 2. The stabilizer 30A “makes frictional contact with the inner periphery of the stent 34.” Sullivan, col. 6, ll. 10-11. The radial force F is exerted on stent by the covering 138 as a reaction force proportional to the spring constant thereof. *See* Sullivan, col. 6, ll. 24-29. The protuberances 38 are said to have “direct contact with sheath 40 as well as still transmit some radial force F indirectly to sheath 40 *through* stent 34. Sullivan, col. 7, ll. 32-35 (emphasis added). The protrusions 58 are described as penetrating “into the *open space 57 between* [stent] elements 19 so that the stent can still rest adjacent inner core 32 without any substantial separation distance added by the rings.” Sullivan, col. 11, ll. 1-5 (emphasis added).

Furthermore, as the passages reproduced above make clear, even assuming *arguendo* that Sullivan did disclose a stent with a covering deformed by protrusions of a pusher or inner catheter, there is no hint or suggestion that the protrusions deform the covering without extending into the luminal envelope of the stent matrix as required by independent claims 1 and 3 or without intersecting a plane along the luminal wall surface as required by independent claims 10 and 19.

Indeed, Sullivan *teaches away* from these features as the stabilizer extends *into* the inner periphery of the stent and makes *frictional contact* therewith.

Accordingly, Applicant submits that a *prima facie* case of obviousness is not established at least because Sullivan does not teach or suggest all of the limitations of the independent claims. Therefore, Applicant submits that claims 1-19 and 21-32 are patentable over Sullivan and requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 103.

Claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sullivan in view of USPN 5,619,878 to Grosjean et al. Applicant respectfully traverses this rejection. Without conceding the propriety of the asserted combination, or accepting the allegations presented in the Office Action, Applicant submits that claim 20 depends from patentable independent claim 19, in view of the above, and is therefore patentable. Accordingly, Applicant requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 103.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 50-2191 referencing docket no. 1016710007P. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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